

## Editorial

# Should balloon angioplasty be used instead of surgery for native aortic coarctation?

Several groups have used transluminal balloon angioplasty of native aortic coarctation to treat aortic coarctation since the technique was first described in the early 1980s. Arguments about whether balloon angioplasty is an effective and safe alternative to surgery have been intensified by reports that aneurysms develop at the site of coarctation dilatation. This editorial sets out the evidence that supports the use of balloon angioplasty as an alternative to surgery.

### Is it effective?

The effectiveness of balloon angioplasty can be evaluated by examining the immediate and follow up results in neonates, infants, and children. The immediate effectiveness is judged on the basis of relief of pressure gradients across the coarctation, the lack of need for immediate surgical intervention, and improvement in symptoms. In 67 patients treated by us, peak-to-peak systolic pressure gradients were significantly reduced from 48 (17) (mean (SD)) to 11 (9) mm Hg immediately after balloon angioplasty.<sup>1</sup> Our results accord with the results of other workers.<sup>2,3</sup> The reduction in gradient was impressive in all age groups: neonates ( $\leq 30$  days), infants (1 to 12 months), and children ( $> 1$  year). Symptoms related to congestive heart failure and/or hypertension, the indications for balloon angioplasty, were relieved<sup>1-3</sup> and only three (6%) of 47 neonates and infants described in published reports,<sup>3</sup> and none from our group, required immediate surgical intervention.

The results of intermediate term follow up indicate that the excellent reduction in gradient was maintained for the group as a whole, but when results of individual patients were scrutinised, recurrence (generally defined as peak-to-peak gradient  $> 20$  mm Hg) was found to be more common in neonates and infants.<sup>1-4</sup> The restenosis rate was particularly high in the neonates; in a pilot study in 10 consecutive neonates Redington *et al* found recoarctations in 5 (71%) of the 7 patients in whom there had been excellent relief of obstruction immediately after balloon angioplasty. They concluded that balloon angioplasty for native aortic coarctation was an unrewarding procedure and that their data did not support the continued use of this technique in neonates. In infants the recoarctation rate was high (about 40%) but is not as high as that seen in neonates. I believe that though the rate of recurrence in neonates and infants is high, balloon angioplasty relieves symptoms and spares the infant a thoractomy. Recoarctation can be treated with repeat balloon angioplasty or surgery<sup>5</sup> at a later date when the patient is older and in a stable condition. Recurrence in children is low.

There are only two long-term ( $> 5$  years) follow up studies,<sup>1,6</sup> and these showed that there was little further recurrence beyond what was observed in the intermediate term ( $\approx 1$  year follow up), an occasional need for re-intervention, and generally well controlled blood pressure.

Our experience and a review of published reports suggest that balloon angioplasty is effective in relieving aortic coarctation.

### Is it safe?

The safety of the procedure may be evaluated by examining the mortality and complication rates, both immediately after the procedure and at follow up. Both immediate and late deaths have been reported in neonates undergoing balloon angioplasty of aortic coarctation. With rare exceptions, these were caused by the associated cardiac defects and not the balloon angioplasty.<sup>7</sup> There were no deaths in older patients.

Arterial complications are likely because balloon-carrying catheters have to be inserted into the femoral artery. Surprisingly, acute arterial compromise (loss of pulse or decreased perfusion) has been minimal. Follow up evaluation showed partial (6%) or complete (8%) occlusion of femoral arteries but without limb growth abnormalities. The arterial complication rate may be further reduced by the recent availability of smaller sized and low-profile balloon catheters. When feasible the umbilical artery<sup>8</sup> should be used in the neonate.

Aneurysms formed at the site of aortic coarctation dilatation in 5-10% of patients. Some were related to angioplasty, but most were probably the result of structural abnormalities of the aortic wall and/or our inability to deliver "controlled injury" to the coarctate aortic segment. The development of aneurysms after balloon therapy is a cause of concern, but aneurysms also occur after coarctation surgery. Late aneurysms have developed most often after repair with synthetic onlay patch grafts, but also have been reported after all other types of repair. In an excellent study Pinzon *et al* reviewed 215 angiograms performed 4.2 (4.1) years after surgical repair of aortic coarctation. They found aneurysms in 64 (30%).<sup>9</sup> The incidence was similar in all three types of commonly used repair methods: 27% (26 of 97) with resection and end-to-end anastomosis, 32% (29 of 92) with subclavian flap repair, and 35% (9 of 21) with synthetic onlay patch repair. These data show that aneurysms occur after all forms of treatment, not solely after balloon angioplasty. They also occur without intervention.<sup>10</sup>

Mortality and complication rates after balloon angioplasty are within an acceptable range and the procedure may be regarded as safe.

### Comparison with surgery

The number of studies comparing the balloon angioplasty procedure with surgical intervention is limited. In an attempt to compare the safety and efficacy of balloon angioplasty with that of surgical correction of aortic coarctation, we scrutinised 49 papers (published 1980-1991) reporting on the results of surgery in infants  $< 1$  year of

age and 9 papers reporting on the results of balloon angioplasty. To have comparable time periods during which both surgical and balloon interventions were performed, we examined the results of infants who underwent coarctation surgery between 1979 and 1990. The prevalence of associated significant heart defects was 70% in both the surgical and balloon angioplasty groups. Initial mortality (7% for balloon *v* 13.5% for surgery;  $P = 0.94$ ) and recoarctation rates (19% for balloon *v* 11.4% for surgery;  $P = 0.74$ ) were similar in both whereas late mortality (4.2% for balloon *v* 12.8% for surgery) was higher ( $P < 0.05$ ) in the surgical group. We did a similar comparison in children (older than 1 year of age) reported in 16 surgical papers published since 1980.<sup>23</sup> Again the initial mortality (0% for balloon *v* 1.3% for surgery;  $P = 0.4$ ) and recoarctation rates (9.5% for balloon *v* 5.9% for surgical group;  $P = 0.98$ ) were similar whereas the late mortality (0% for balloon *v* 5.6% for the surgical group;  $P < 0.01$ ) was higher for the surgical group. Thus in both age groups comparison of published studies showed similar recoarctation rates but slightly higher mortality in the surgical series.

Shaddy *et al* randomised 36 patients, aged 3–10 years, to either balloon angioplasty (20 patients) or surgery (16 patients) and found similar immediate relief of the pressure gradient in both groups.<sup>11</sup> The risks of aneurysm formation and restenosis were higher in the balloon angioplasty group, whereas the risks of neurological complications were higher in the surgical group. They concluded that balloon angioplasty of coarctation of the aorta may provide an effective initial alternative to surgery in children beyond infancy, and suggested further follow up is needed to evaluate the long-term risks of aneurysms after angioplasty.

We compared the efficacy and safety of balloon angioplasty with that of surgical correction in infants  $\leq 3$  months of age by examining data on 29 infants undergoing treatment for aortic coarctation during the decade ending 1992. Fourteen underwent surgical repair while 15 had balloon angioplasty. The surgical and balloon groups were similar with regard to age, weight, and prevalence and type of associated defects. Operative mortality, late mortality, immediate peak systolic pressure gradient relief (36 (25) to 10 (9) *v* 41 (14) to 6 (6) mm Hg), and follow up gradients (27 (27) *v* 24 (19) mm Hg) were similar. The proportion of infants with gradients  $> 20$  mm Hg at follow up and need for re-intervention were also similar in both groups. However, the duration of hospital stay for the first intervention was higher ( $P = 0.05$ ) for the surgical group (32 (27) days) than for the balloon group (7 (6) days). Similarly, the surgical group needed endotracheal intubation and mechanical ventilation for longer than the balloon group (12 (16) *v* 2 (3) days,  $P < 0.05$ ). There were complications after surgery, namely cardiac arrest, acute renal failure, a central nervous system event, tension pneumothorax, septicaemia, and paradoxical hypertension in two patients each (0.86 events per patient). This rate was significantly higher ( $P = 0.05$ ) than that seen with balloon angioplasty, namely, femoral artery compromise (loss of pulse or decreased perfusion) and blood loss requiring transfusion in two infants each (0.27 events per patient). The degree of relief of aortic coarctation and the frequency with which re-intervention was needed were similar in both groups. However, morbidity and complications were less common with angioplasty than with surgery. These data led us to suggest that balloon angioplasty may be an acceptable alternative to surgery in the treatment of symptomatic aortic coarctation in infants  $\leq 3$  months of age.<sup>7</sup>

Some of the complications, namely, recoarctation, aneurysm formation, and femoral artery compromise, have been discussed above. Other complications such as paraplegia and paradoxical hypertension are often seen after surgical repair whereas such complications are rare or, if present, very mild and inconsequential after balloon angioplasty.

The review of published studies<sup>23711</sup> suggests that mortality is similar (and probably related to the associated cardiac defects rather than the type of intervention performed) and morbidity and complication rates are lower with angioplasty than with surgery. Balloon angioplasty seems to be an effective alternative to surgery for the relief of aortic coarctation.

## Conclusions

The data that I have reviewed show that balloon angioplasty is an effective procedure in relieving the obstruction and the attendant symptoms caused by native coarctation. Mortality and complication rates after balloon angioplasty are not high, and therefore the procedure may be considered safe. There is a significant incidence of recoarctation in the neonate and young infant. But the important feature of balloon angioplasty in the neonate and young infant is that, because it relieves symptoms of heart failure and hypertension, it helps to avoid immediate surgery. Recurrence, should it occur, can be treated by repeat balloon angioplasty or even surgery when the infant is stable and less acutely ill. The development of aneurysms at the site of balloon angioplasty is a cause for concern and patients in whom aneurysms develop should have periodic evaluation of their size or surgical resection should be performed. Aneurysms, though of concern, have also been seen after all varieties of surgical correction. Comparison with surgery, though limited, has similar mortality and recurrence rates but with less morbidity in the balloon group than in the surgical group. Because balloon angioplasty requires fewer days in hospital it is likely to cost less. These data indicate that balloon angioplasty is an effective and safe alternative to surgical treatment of native coarctation.

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